DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER

VIA FEDERAL EXPRESS

March 17, 2003

Edward B. Diethrich, M.D.
Arizona Heart Institute
Interventional Research Department
1910 East Thomas Road
Phoenix, AZ 85016

Dear Dr. Diethrich:

The purpose of this Warning Letter is to inform you of violative conditions found during a Food and Drug Administration (FDA) inspection at your clinical site and to request immediate corrective actions.

During the period of October 22 through November 01, 2002, Dr. Sandra Shire, an investigator from the FDA, Los Angles District Office, conducted the inspection. The purpose of the inspection was to determine whether your activities as a sponsor and principal investigator of investigational studies with significant risk devices complied with applicable FDA regulations. The inspection reviewed your research and use of significant risk study devices intended for use in the treatment of [redacted]

The inspection was conducted under a program designed, in part, to ensure that data and information contained in applications for Investigational Device Exemptions (IDEs) are scientifically valid and accurate. Another objective of this program is to ensure that human subjects are protected from undue hazard or risk during the course of the scientific investigations.

The inspection at Arizona Heart Institute (AHI) covered four protocols having Investigational Device Exemptions (IDEs): [redacted] The products used in these studies are devices as that term is defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S. C. 321(h)].

During the inspection, the FDA investigator documented that you treated approximately [redacted] subjects diagnosed with a [redacted] with an unapproved, significant risk medical device manufactured by [redacted] These subjects were treated with an endoluminal graft deployed to their [redacted]. This device has not been approved by FDA for this or any other use, nor has an IDE been approved permitting its investigational use. Although other concerns were raised during the course of this inspection, this letter addresses your use of the [redacted]

In your written response to the inspection, you state that the [redacted] device did not need an approved IDE because the [redacted] were custom devices. The custom device exemption applies to devices that meet a narrow and specific set of statutory requirements. The devices you implanted did not meet these requirements: they were simply ordered individually from existing pre-manufactured stock.

Continued implantation of these devices will be considered by FDA to be knowingly violating the Food, Drug, and Cosmetic Act. Please submit a written response to this letter, identifying all human subjects who received the [redacted] or any other unapproved device, by name, address and date of implantation. To protect the rights and welfare of the human subjects you implanted, you must develop a corrective action plan that includes, at a minimum, notification of each recipient by certified mail that they were implanted with an unapproved device, who to contact in the event of an emergency, and where to report adverse events. Your corrective action plan should be submitted to this office for approval prior to implementation. Copies of all letters sent to implant recipients should also be submitted to this office.

The deviations cited above are not intended to be an all-inclusive list of deficiencies at your site. As a clinical investigator, it is your responsibility to ensure that investigations that you participate in are conducted in accordance with applicable FDA regulations.

Within 15 days, you must respond to this letter in writing. You should be aware that FDA considers your actions to be serious violations of the law and your failure to respond may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, investigator disqualification, seizing product inventory, obtaining an injunction to prevent further violations of the law, assessment of civil money penalties, and criminal prosecution.

You should direct your response to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Bioresearch Monitoring, Program Enforcement Branch I (HFZ-311), 2098 Gaither Road, Rockville, Maryland 20850. Attention: Doreen Kezer, MSN, Consumer Safety Officer.

A copy of this Warning Letter was sent to the Food and Drug Administration's Los Angeles District, 4510 Executive Drive, Suite 225, San Diego, CA 92121-3023. We request that a copy of your response also be sent to that office.

Please direct all questions concerning this matter to Ms. Kezer at (301)594-4720, ext. 131.

Sincerely yours,

Michael E Marcarelli

for Timothy A. Ulatowski
Director
Office of Compliance
Centers for Devices and
Radiological Health

cc: PURGED COPIES

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